

47. The method according to Claim 15 wherein the living thing is an animal, avian species or plant.

48. The method according to Claim 21, wherein the autoimmune disease is selected from the group consisting of: Type 1 diabetes, multiple sclerosis, myasthenia gravis, pernicious anaemia, psoriasis, rheumatoid arthritis, scleroderma and systemic lupus erythematosus.

49. The method according to Claim 21, wherein the pathogen is selected from the group consisting of: a virus, a bacteria, a protozoan, and a fungus.

50. The method according to Claim 21, wherein the virus is selected from the group consisting of: HIV-1, Hepatitis virus, and Epstein-Barr virus.

51. The method according to Claim 21, wherein the protozoan is the malaria parasite.

52. The method according to Claim 22, wherein the antigens are expressed on the surface of a normal or cancer cell or are released by a normal or cancer cell.

53. An assay device according to Claim 1 wherein the binding of a binding partner to an immobilized molecule is determined using a labeled antibody to the same binding partner or to a different partner associated with said first binding partner.

54. An assay device according to Claim 2 wherein the binding of a binding partner to an immobilized molecule is determined using a labeled antibody to the same binding partner or to a different partner associated with said first binding partner.

55. A method according to Claim 27 wherein the binding of a binding partner to an immobilized molecule is determined using a labeled antibody to the same binding partner or to a different partner associated with said first binding partner.

IN THE ABSTRACT

Please insert the attached "Abstract of the Invention" after the last page of the claims.

REMARKS

The claims and specification have been amended to conform to the rules of practice before the United States Patent and Trademark Office. Claim 30 has been deleted and Claims 36-55 added. Support for the added and amended claims can be found in the claims as filed. No new matter has been added herewith.

The changes made to the claims by the current amendment, including deletions and additions, are shown on an attached sheet entitled **VERSION WITH MARKINGS TO SHOW CHANGES MADE**, which follows the signature page of this Amendment.

Int'l Appl. No. : PCT/AU99/01156
Date : December 23, 1999

Conclusion

Should there be any questions in response to the above-identified patent application, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 25 June 2001

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Please cancel Claim 30.

Please amend the remaining claims as follows:

1. (Amended) An assay device comprising an array of non-nucleic acid molecules wherein each molecule in the array, with the exception of a negative control, is capable of interaction with its respective binding partner **[putatively]** in a biological sample **[from an animal, avian species or plant]** and wherein the pattern of interaction between the molecules and the binding partners is indicative of a **[normal]** condition **[or a disease condition or disorder or a propensity for the development of a disease condition or disorder]**.
2. (Amended) An assay device comprising an array of non-nucleic acid molecules wherein each molecule in the array, with the exception of a negative control, is capable of interaction with its respective binding partner **[putatively]** in a chemical library, phage display library or environmental sample, and wherein the pattern of interaction between the molecules and the binding partners is indicative of **[the presence, type and/or amount of]** a particular binding partner in said sample.
5. (Amended) An assay device according to Claim **[4]**1, wherein the disease condition or disorder is cancer.
6. (Amended) An assay device according to Claim **[4]**1, wherein the binding partner is an antigen **[is a chemical in a chemical library or in an environmental sample or is a peptide, polypeptide or protein in a phage display library]**.
7. (Amended) An assay device according to Claim **[4]**1, wherein the array comprises immunoglobulins in discrete regions of **[the]**a solid support and the binding partners are antigens expressed on the surface of or released by a **[normal or cancer]** cell **[or are released by a normal or cancer cell or are present on a microbe, virus, parasite or other pathogen or is a chemical in a chemical library or in an environmental sample or is a peptide, polypeptide or protein in a phage display library]**.
8. (Amended) An assay device according to Claim 7 wherein the array comprises the formula:

$$\left[\left[q_{0,1} \right]_{i_1}^{m_1} \left[q_{0,2} \right]_{i_2}^{m_2} K \left[q_{0,3} \right]_{i_3}^{m_3} \right]_{i_4}$$

wherein

q is an immunoglobulin specific for an antigen [expressed on a normal cell or cancer cell or antigen released by a normal cell or cancer cell or an antigen present on a microbe, virus, parasite or other pathogen or is a chemical in a chemical library or in an environmental sample or is a peptide, polypeptide or protein in a phage display library];

m_1, m_2, \dots, m_i represent members of the same immunoglobulin group which bind different parts of the same antigen;

$0_1, 0_2, \dots, 0_k$ represent different groups of immunoglobulins defined by specificity to different antigens;

e, f and g represent the number of different immunoglobulins within each of groups $0_1, 0_2, \dots, 0_k$, respectively and wherein e, f and g may be the same or different and each is from 0 to 1-- provided that at least one of e, f, and g is not 0;

y is the total number of groups of immunoglobulins on the array and is from about 2 to about 2000.

10. **(Amended)** An assay device according to Claim 8 [or 9], wherein the immunoglobulins are specific for an antigen selected from the group consisting of: the cluster of differentiation (CD) antigens, [and/or] myeloid (MY) antigens and [or] lymphoid (LY) antigens expressed on leukemic cells.

11. **(Amended)** An assay device according to Claim 1, wherein the disease [condition] or disorder is [a] non-neoplastic [disorder].

12. **(Amended)** An assay device according to Claim 11, wherein the [disease or condition is a] non-neoplastic disease or disorder [of the] is a disease or disorder of the immune system.

13. **(Amended)** An assay device according to Claim 11 [or 12] wherein the disease [or condition] is selected from the group consisting of: an autoimmune disease [such as Type 1 diabetes, multiple sclerosis, myasthenia gravis, pernicious anaemia, psoriasis, rheumatoid arthritis, scleroderma and systemic lupus erythematosus], infection by a pathogen [such as a virus including HIV-1, Hepatitis virus, Epstein-Barr virus (mononucleosis), a microorganism or a malarial parasite], congenital immunodeficiency, adverse reaction following bone marrow or tissue transplantation [or] and chronic fatigue syndrome.

14. (Amended) An assay according to **[any one of Claims 1 to 13]** Claim 1 or 2 wherein the non-nucleic acid molecules are immobilized on **[the]** a solid support and are in an arrangement in the array such that upon interaction between the molecules and the binding partners, a differential pattern of density provides an identifiable signal.

15. (Amended) A method for determining the presence of a disease condition or disorder or a propensity to develop a disease condition or disorder **[such as but not limited to cancer or a non-neoplastic disorder in an animal, avian species or plant]** in a living thing, said method comprising:

obtaining a biological sample from said **[animal, avian species or plant]** living thing comprising free binding partners or binding partners bound to a cell surface associated directly or indirectly with said disease condition or disorder; and

contacting said biological sample with a solid support comprising an array of non-nucleic acid molecules capable of binding to said binding partners wherein the pattern of interaction with the binding partners is indicative of the disease condition or disorder or a propensity to develop said disease condition or disorder.

17. (Amended) A method according to Claim **[16]** 15 wherein the array comprises the formula:

$$\left[\left[P_{x_1} \right]_b^{n_1} \left[P_{x_2} \right]_c^{n_2} \dots \left[P_{x_j} \right]_d^{n_j} \right]_z$$

wherein

P is a member of a binding group capable of interacting with a binding partner;

$n_1 \ n_2 \ \dots \ n_i$ represent different members of the binding group;

$x_1 \ x_2 \ \dots \ x_i$ represent different binding groups;

b, c and d represent the number of different members of the binding groups $x_1 \ x_2 \ \dots \ x_j$; respectively and wherein b, c and d may be the same or different and each is from about 0 to about 100 provided that at least one of b, c or d is not 0;

z is the total number of groups of molecules on the array and is from about 2 to about 2000.

18. (Amended) A method **[of]** according to Claim 17, wherein the disease condition or disorder is cancer.

21. (Amended) **[An assay device according to Claim 20]** The method of Claim 19, wherein the disease or condition is selected from the group consisting of: an autoimmune

disease [such as Type 1 diabetes, multiple sclerosis, myasthenia gravis, pernicious anaemia, psoriasis, rheumatoid arthritis, scleroderma and systemic lupus erythematosus], infection by a pathogen [such as a virus including HIV-1, Hepatitis virus, Epstein-Barr virus (mononucleosis), a microorganism or a malarial parasite] congenital immunodeficiency, adverse reaction following bone marrow or tissue transplantation [~~or~~and] chronic fatigue syndrome.

22. (Amended) A method according to Claim 15, wherein the array comprises immunoglobulins in discrete regions of [the]a solid support and the binding partners are antigens [expressed on the surface of a normal or cancer cell or are released by a normal or cancer cell].

23. (Amended) A method according to Claim [22]15 wherein the array comprises the formula:

$$\left[\left[q_{0_1} \right]_e^{m_1} \left[q_{0_2} \right]_f^{m_2} \cdots \left[q_{0_k} \right]_g^{m_k} \right]_y$$

wherein

q is an immunoglobulin specific for an antigen expressed on a normal cell or cancer cell or antigen released by a normal cell or cancer cell or an antigen present on a microbe, virus, parasite or other pathogen or is a chemical in a chemical library or in an environmental sample or is a peptide, polypeptide or protein in a phage display library;

$m_1 m_2 \dots m_i$ represent members of the same immunoglobulin group which bind different parts of the same antigen;

$0_1 0_2 \dots 0_k$ represent different groups of immunoglobulins defined by specificity to different antigens;

e, f and g represent the number of different immunoglobulins within each of groups $0_1 0_2 \dots 0_k$, respectively and wherein e, f and g may be the same or different and each is from 0 to 1-- provided that at least one of e, f, and g is not 0;

y is the total number of groups of immunoglobulins on the array and is from about 2 to about 2000.

25. (Amended) A method according to Claims [23 or 24]22 wherein the immunoglobulins are specific for any antigens selected from the group consisting of: cluster of

differentiation (CD) antigens, [and/or] myeloid (MY) antigens, [or] lymphoid (LY) antigens expressed on leukemic cells.

26. (Amended) A method according to [any one of Claims 15 to 25] Claim 15, wherein the molecules immobilized on the solid support are in an arrangement in the array such that upon interaction between the molecules and the binding partners, a differential pattern of density provides an identifiable signal.

27. (Amended) A method of treating cancer or a propensity to develop cancer in a human or non-human animal, said method comprising:

obtaining a biological sample from said human or non-human animal; and
contacting said sample with an array of immunoglobulin molecules or functional derivatives or equivalents thereof immobilized to discrete regions of [the] a solid support such that different discrete regions have specificity for different antigens and wherein the antigens are expressed on the surface of normal cells or cancer cells or are released by normal cells or cancer cells, and

determining the binding pattern of the immobilized immunoglobulins to their respective antigens; and [then]

undertaking immunotherapy based on the expression of the antigens.

28. (Amended) A method according to [any one of Claims 1 to 27] Claim 15 wherein the binding of a binding partner to an immobilized molecule is determined using a labeled antibody to the same binding partner or to a different partner associated with said first [mentioned] binding partner.

31. (Amended) A method for identifying a protein mimetic in a chemical or biological sample said method comprising:

contacting said sample with an array of immobilized molecules capable of binding to the protein for which a mimetic is sought; and

identifying the presence of a protein mimetic which binds to an immobilized molecule.

33. (Amended) A method according to Claim 31 [or 32] wherein the chemical sample is a synthetic or natural chemical library.

34. (Amended) A method according to Claim 31 [or 32], wherein the biological sample is a phage display library.

35. (Amended) A method according to Claim 31 [or 32] wherein the protein mimetic is capable of activating or antagonizing a B or T lymphocyte.

Please add the following claims:

36. The assay device of Claim 1, wherein the biological sample is from an animal, avian species, or plant.

37. The assay device of Claim 1, wherein the condition is selected from the group consisting of: a normal condition, a disease condition, a disorder, and a propensity for the development of a disease or disorder.

38. The assay device of Claim 2, wherein the pattern is further indicative of the type and/or amount of the binding partner.

39. The assay device of Claim 6, wherein the antigen is a chemical or wherein the antigen is a peptide, or a polypeptide in a phage display library.

40. The assay device of Claim 39, wherein the chemical is from a chemical library or an environmental sample.

41. The assay device according to Claim 1, wherein the array comprises immunoglobulins in discrete regions of the solid support and the binding partners are chemicals or a peptide or polypeptide in a phage display library.

42. The assay device according to Claim 41, wherein the chemicals are in a chemical library or an environmental sample.

43. The assay device according to Claim 13, wherein the autoimmune disease is selected from the group consisting of: Type 1 diabetes, multiple sclerosis, myasthenia gravis, pernicious anaemia, psoriasis, rheumatoid arthritis, scleroderma and systemic lupus erythematosus.

44. The assay device according to Claim 13, wherein the pathogen is selected from the group consisting of: a virus, a bacteria, a protozoan, and a fungus.

45. The assay device according to Claim 44, wherein the virus is selected from the group consisting of: HIV-1, Hepatitis virus, and Epstein-Barr virus.

46. The assay device according to Claim 44, wherein the protozoan is the malaria parasite.

47. The method according to Claim 15 wherein the living thing is an animal, avian species or plant.

48. The method according to Claim 21, wherein the autoimmune disease is selected from the group consisting of: Type 1 diabetes, multiple sclerosis, myasthenia gravis, pernicious anaemia, psoriasis, rheumatoid arthritis, scleroderma and systemic lupus erythematosus.

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53. An assay device according to Claim 1 wherein the binding of a binding partner to an immobilized molecule is determined using a labeled antibody to the same binding partner or to a different partner associated with said first binding partner.

54. An assay device according to Claim 2 wherein the binding of a binding partner to an immobilized molecule is determined using a labeled antibody to the same binding partner or to a different partner associated with said first binding partner.

55. A method according to Claim 27 wherein the binding of a binding partner to an immobilized molecule is determined using a labeled antibody to the same binding partner or to a different partner associated with said first binding partner.